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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/855,945	05/14/2001	Clifton A. Alferness	1931-2	1454

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EXAMINER

CHATTOPADHYAY, URMI

ART UNIT	PAPER NUMBER
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3738

DATE MAILED: 11/18/2003

16

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/855,945

Applicant(s)

ALFERNESS ET AL.

Examiner

Urmi Chattopadhyay

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 05 September 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,2,4-15,41,42 and 44-73 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2,4-15,41,42 and 44-73 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 14 May 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 14.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

## **DETAILED ACTION**

### ***Response to Amendment***

1. The amendment filed 9/5/03 has been entered as Paper No. 15. The changes made to claims 1 and 41 have been approved by the examiner, and claims 58-73 have been added. All pending claims are being considered for further examination on the merits, which include 1, 2, 4-15, 41, 42 and 44-73.

### ***Terminal Disclaimer***

2. The terminal disclaimers filed on 3/7/03 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of any patent granted on application numbers 09/855,946 and 09/751,271 have been reviewed and is accepted. The terminal disclaimers have been recorded.

### ***Information Disclosure Statement***

3. The information disclosure statement filed 6/23/03 fails to comply with 37 CFR 1.97(d) because the statement provided does not meet the requirements as specified in 37 CFR 1.97(e). It has been placed in the application file, but the information referred to therein has not been considered.

4. Applicant is reminded that under 37 C.F.R 1.97(e), certification must state either:

(1) That each item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the statement, or

(2) That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application or, to the knowledge of the person signing the certification after making reasonable inquiry, was known to any individual designated in § 1.56(c) more than three months prior to the filing of the statement.

***Claim Rejections - 35 USC § 102***

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 1, 4-7, 9-11, 15, 41, 44-47, 49-51, 55-62, 64-66 and 68-73 are rejected under 35 U.S.C. 102(e) as being anticipated by Langberg et al. (USPN 6,402,781 as cited in last office action).

Langberg et al. discloses an assembly for effecting the condition of a mitral valve annulus and a mitral valve annulus constricting or therapy device with all the elements of claims 1, 41, 56 and 57. See column 10, lines 40-44 for a guide wire configured to be fed into the coronary sinus

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of the heart and a mitral valve annulus device (66) configured to be slidably received on the guide wire and advanced into the coronary sinus of the heart on the guide wire and that reshapes the mitral valve annulus when in the coronary sinus of the heart (see abstract). The guide wire lumen that extends from one end of the device to an opposing end forms a guide wire engaging structure at at least one of the ends thereof. See column 11, lines 50-61 for the mitral valve annulus device being resilient and configured to be deformed. For claims 56 and 57, see Figure 2 for device having an arched configuration and being a generally C-shaped member.

Claims 4-7, 44-47 and 58-61, see column 10, lines 40-44. The lumen, which is inherently cylindrical in shape, defines bores at each of the ends of the device, which are dimensioned to permit the guide wire to pass therethrough, and a channel extending between and aligned with the bores.

Claims 9, 10, 49, 50 and 62, see column 11, lines 52-54 for device (66) having a metal core, and metal is inherently visible under X-ray fluoroscopy.

Claims 11 and 51, see Figure 4 for an elongated introducer (86) having a lumen (88), thereby making it capable of being slidably received on the guide wire proximal to the device.

Claims 15 and 55, see Figure 3 and column 10, lines 54-60 and column 11, lines 18-20 for guide tube (74) having an inner lumen (84).

Claims 64-66 and 68-73, see column 11, lines 50-61. The device is configured to be in a deformed configuration while being advanced into the coronary sinus and change to an unstressed arched shape having a smaller radius than mitral valve annulus to remodel the annulus when in the coronary sinus of the heart.

***Claim Rejections - 35 USC § 103***

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 2, 8, 12, 42, 48 and 52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Langberg et al. in view of de Toledo et al. (USPN 4,830,023 as cited in last office action).

Langberg et al. discloses an assembly for effecting the condition of a mitral valve annulus with all the elements of claims 1 and 41, but is silent to the guide wire being formed of a material visible under X-ray fluoroscopy, and the guide wire and introducer being an elongated coil, as required by claims 8, 48 and 2, 12, 42, 52, respectively. de Toledo et al. teaches a metal guide wire (claims 8 and 48) being an elongate coil in order for it to have greater flexibility (claims 2, 12, 42 and 52). See abstract. Because both the guide wire and introducer of Langberg et al. require flexibility to travel through the venous system into to the coronary sinus, it would have been obvious to one of ordinary skill in the art at the time of applicant's invention to look to the teachings of de Toledo et al. to modify the guide wire so that it is made of metal, and therefore by nature visible under X-ray fluoroscopy, and the guide wire and introducer of Langberg et al. such that they are elongated coils in order for them to have greater flexibility for the travel.

9. Claims 13, 14, 53, 54, 63 and 67 are rejected under 35 U.S.C. 103(a) as being unpatentable over Langberg et al. in view of Taylor et al. (2002/0183835 as cited in last office action).

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Langberg et al. discloses an assembly and device for effecting the condition of a mitral valve annulus with all the elements of claims 1, 41, 56 and 57, but is silent to a releasable locking mechanism configured to releasably lock the proximal end of the device to the distal end of the introducer, as required by claims 13, 53, 63 and 67. Taylor et al. teaches an assembly for effecting the condition of a mitral valve annulus and a mitral valve annulus constricting or therapy device that uses a locking mechanism to releasably lock the proximal end (190) of the device to the distal end of the introducer (187) in order to for the device to be pulled backward within the coronary sinus, either for positioning or removal purposes. See [0098]. It would have been obvious to one of ordinary skill in the art at the time of applicant's invention to look to the teachings of Taylor et al. to modify the assembly and device of Langberg et al. by adding a releasable locking mechanism to releasably lock the device to the introducer in order to pull the device backwards within the coronary sinus for positioning or removal purposes. Taylor et al. does not disclose expressly that the releasable locking mechanism is a locking pin and a complimentary dented locking groove, as required by claims 14 and 54. At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to have the locking mechanism include a locking pin and complimentary dented locking groove because applicant has not disclosed that pin and groove provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art would have expected applicant's invention to perform equally well with the grasper of Taylor et al. or any other attachable interface known in the art because the ability for the device to be repositioned or removed is not affected by the type of releasable locking mechanism used

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between the device and introducer. Therefore, it would have been an obvious matter of design choice to modify Taylor et al. to obtain the invention as specified in claims 14 and 54.

### ***Response to Arguments***

10. Applicant's arguments filed 9/5/03 have been fully considered but they are not persuasive. Applicant argues that none of the cited art of record shows, describes or even suggests a mitral valve annulus device that is resilient. The examiner disagrees. As explained in the above rejection, Langberg et al. discloses an embodiment wherein "a core of springy memory material such as nitinol or other NiTi alloy is pre-formed to have the required configuration" replaces the axially moveable forming element (column 11, lines 50-61). In this embodiment, the device is indeed resilient and is capable of being used in the manner claimed.

### ***Conclusion***

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

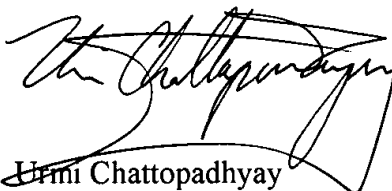


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however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

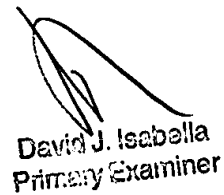
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ms. Urmi Chattopadhyay whose telephone number is (703) 308-8510 and whose work schedule is Monday-Friday, 9:00am – 6:30pm with every other Friday off. The examiner's supervisor, Corrine McDermott, may be reached at (703) 308-2111. The group receptionist may be reached at (703) 308-0858.

Should the applicant wish to send a fax for official entry into the file wrapper the Group fax number is (703) 872-9306. Should applicant wish to send a fax for discussion purposes only, the art unit fax number is (703) 308-2708.



Urmi Chattopadhyay

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David J. Isabella  
Primary Examiner